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MINNEAPOLIS, MN 55403-2420

EXAMINER
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DESANTO, MATTHEW F

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3763

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/498,104  
Filing Date: February 04, 2000  
Appellant(s): SCOPTON, PAUL M

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David Crompton  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 1/14/05.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is substantially correct.

Claims 1-5, 7-9 rejected.

Claims 10-13 and 15-17 are in condition for allowance.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is substantially correct.

1. Whether claims 1-5, are anticipated under 32 USC 102 (e) by Sirhan (U.S. Patent No. 5,984,945).

2. Whether claims 1-5, 7 are anticipated under 35 U.S.C. 102(b) by Crittenden et al. (U.S. Patent No. 4,988,356).

3. Whether claims 1-5, and 7-9, are anticipated under 35 U.S.C. 102(b) by Horzewski et al. (U.S. Patent No. 4,771,777).

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

5,984,945	Sirhan	11-1999
4,988,356	Crittenden et al.	1-1991
4,771,777	Horzewski et al.	9-1988

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

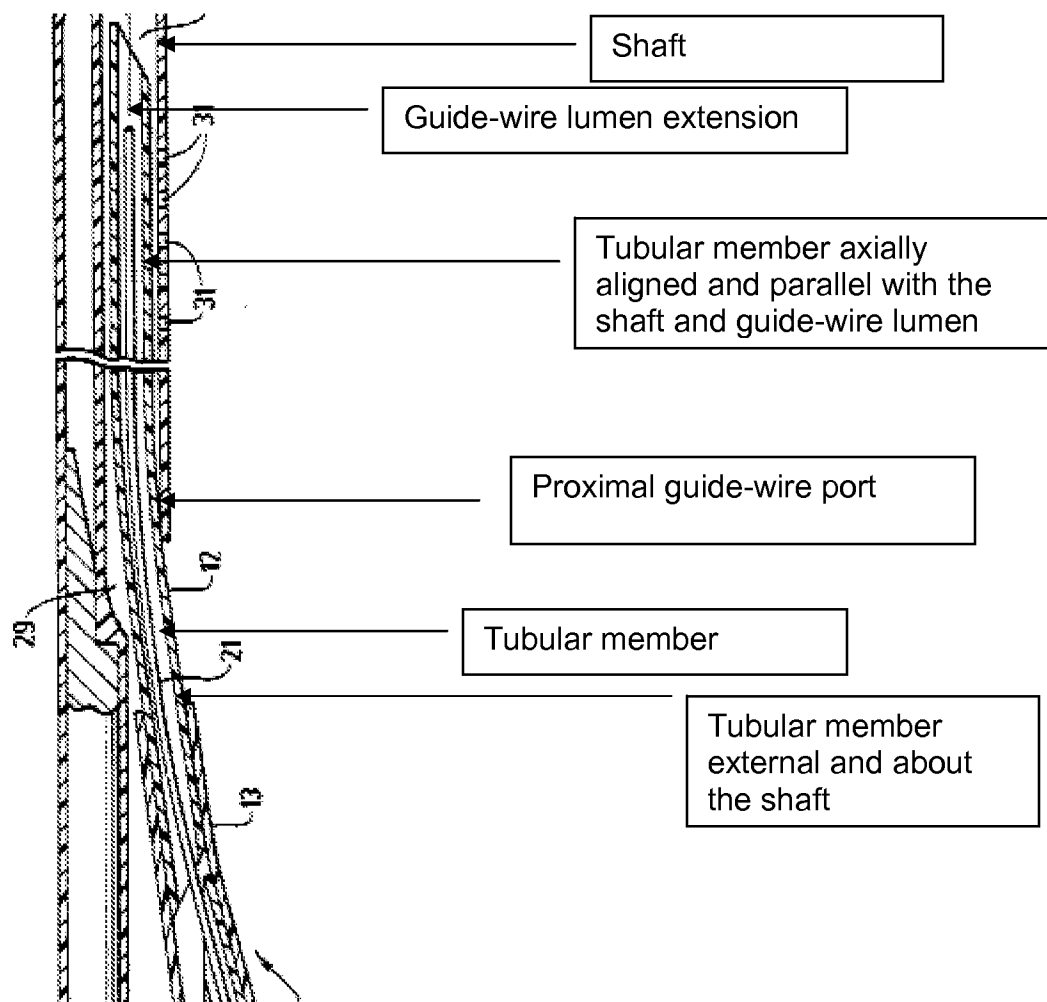
Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan (USPN 5,984,945). This rejection is set forth in a prior Office Action, mailed on 11/24/03.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan discloses a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen (30) extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the

shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein (Figures 6, 7-10, 15 and entire reference).

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein (Figures 6, 7-10, 15 and entire reference).

Art Unit: 3762



Claims 1, 2, 3, 4, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Crittenden et al. (4988356). This rejection is set forth in a prior Office Action, mailed on 11/24/03.

Crittenden et al. discloses et al. a biliary catheter comprising an elongated shaft (10) having a proximal end, a distal end, and an injection lumen (22) extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen (26) being in fluid communication with the injection lumen of the shaft (Column 2, lines 42-45), the proximal guidewire port (is the area where the guidewire extension [50] enters the guidewire lumen) disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port (18) disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member (12) extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein.

Wherein the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein.

Wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port, and where the tubular member has as length of approximately 5-30 cm and a heat shrink tube (Figures 1, 7, 9, 11, 12 and entire reference).

Figure 2, shows the injection lumen (22).

Figure 9, shows the radially shift that occurs in the shaft.

Claims 1-5, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski et al. (4,771,777). This rejection is set forth in a prior Office Action, mailed on 11/24/03.

Horzewski et al. discloses a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port (47) and a distal guidewire port (33), the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member (71) defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein (Figures 1-4 and entire reference).

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein (Figures 1-4 and entire reference).



Art Unit: 3762

Wherein the guidewire lumen extension is axially aligned with the guidewire port.

**(11) Response to Argument**

A. The applicant argues that the prior art reference Sirhan (USPN 5,984,945) fails to disclose a guidewire lumen extension that is external and parallel to the shaft, and is axially aligned with the guidewire lumen. The examiner disagrees and suspects that the applicant is reading limitations of the specification into the claim. The claim does not state that the entire guidewire lumen extension has to be external and the entire guidewire lumen extension has to be parallel to the shaft. The figure above, shows portions of the guidewire lumen extension that is parallel to the shaft as well as a portion of the guidewire lumen extension that is external to the shaft, as well as wherein the guidewire lumen extension is axially aligned with the guidewire lumen. Therefore, the prior art references teach the limitations of the claim. The prior art also shows the tubular member and shaft are “connected” since once part of the tubular member is inserted into the shaft.

With regards to claims 3, the term “about” is being interpreted “as reasonably close to” (as defined by Webster’s online dictionary) and therefore, the tubular member is reasonably close to the shaft. This can be seen in Figure 15.

With regards to claims 4, the distal end is fluidly sealed about the shaft, since any fluid that exists the guide wire lumen extension has to be transferred to the shaft, therefore, making the distal end of the guidewire lumen extension fluidly sealed about the shaft. This can be seen in Figure 15.

With regards to claims 5, the examiner understands the interpretation of the applicant, but fails to give the full scope as interpreted by the applicant. The guidewire

lumen extension is smaller than the guide wire lumen and has walls which would create a restriction flow since the fluid or element has to be contained within the guide wire lumen extension. This can be seen in Figure 15.

With regard to claim 7, the examiner has withdrawn claim 7 from the rejection because of further consideration and arguments in the brief.

B. The applicant argues that Crittenden et al. (USPN 4,988,356) fails to disclose a catheter shaft having a proximal guidewire port and a distal guidewire port. This can be seen in the figure 1 and 7. The proximal guidewire port occurs at reference number 50, which can be seen in figure 7. This port allows the guidewire to enter the guidewire lumen as seen in figure 9. The distal port occurs at reference number 18, which can be seen in Figure 1. The examiner would like to elaborate on this interpretation as well as comment on the reply brief and the appeal brief. In Crittenden et al. the shaft has a slit (28) that separated as shown in figure 10 to form a discrete opening for the guidewire lumen extension (48) to enter the guidewire lumen. The location where this occurs is the proximal guidewire port, because a discrete opening is formed as shown in figure 10. The location in which the guidewire lumen extension and guidewire lumen meet form the guidewire proximal port because the guidewire lumen has to have a proximal port at this location so that the guidewire can pass from the tubular member into the guidewire lumen. Therefore the examiner stated that the guidewire port occurs at reference number 50 because this was the closest reference number to the location where the guidewire lumen extension and guidewire lumen come into contact.

C. The applicant argues that Horzewski et al. fails to teach a catheter shaft having an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, and a tubular member extending proximally from the proximal guidewire port defining a guidewire lumen extension in fluid communication with the guidewire lumen. The examiner disagrees with this assertion, and the structurally elements can be seen in figures 1 and 4.

The applicant next argues that the tubular member is not “connected to the proximal guidewire port” but this is not the limitation in the claim. The limitation is the tubular member “extends” proximally from the proximal guidewire port, which can be seen in Figure 1 and 4. The tubular member extends proximally from the proximal port to the distal end of the shaft.

The applicant’s next argument is that the tubular member and the guidewire lumen are not in fluid communication. The examiner disagrees because if fluid were injected into the tubular member, some fluid would flow into the guidewire lumen, thus making the tubular member and the guidewire lumen in fluid communication. The examiner also interprets this limitation to be functionally and therefore the tubular member is capable of transferring fluid from the tubular member to the guidewire lumen.

With regards to claims 3, the term “about” is being interpreted “as reasonably close to” (as defined by Webster’s online dictionary) and therefore, the tubular member is reasonably close to the shaft. This can be seen in Figure 4.

With regards to claims 4, the distal end is fluidly sealed about the shaft, since fluid would be sealed between the tubular member and the shaft because any fluid that is in the tubular member would be trapped in the bottom of the tubular member, which does not have a slit. This can be seen in Figure 2.

With regards to claims 5, there is no structure associate with this claim, and since the guidewire lumen extension is smaller then the guide wire lumen, it is inherently capable of being sized to restrict the guide wire. This can be seen in Figure 1, 4.

Claims 10-13, 15-17 are allowable.

For the above reasons, it is believed that the rejections should be sustained.

Application/Control Number: 09/498,104  
Art Unit: 3762

Page 13

Respectfully submitted,

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Art Unit 3763  
April 17, 2008

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Application/Control Number: 09/498,104  
Art Unit: 3762

Page 14

MINNEAPOLIS, MN 55403-2420